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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,554	11/03/2000	Lawrence Friedhoff	0200-0004	4555

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11/19/2002

TransPotomac Plaza  
1033 N Fairfax Street  
Suite 306  
Alexandria, VA 22314

EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/704,554

Applicant(s)

FRIEDHOFF ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 60-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 3, 2002 has been entered in Paper No. 15.

This Office Action is a response to Applicant's request for continued examination (RCE) filed September 3, 2002, and amendment and response to the Final Office Action (mailed March 27, 2002), filed July 29, 2002 in Paper No. 12 wherein claims 36-59 are cancelled, and claims 60-83 are newly submitted. Currently, claims 60-83 are pending in this application.

The declaration of Dr. Edward Cullen under 37 CFR 1.132 submitted July 29, 2002 is acknowledged and will be discussed further.

Applicant's amendment filed July 29, 2002 in Paper No. 12 canceling 36-59 with respect to the rejection of claims 36-59 made under 35 U.S.C. 103(a) as being unpatentable over Scolnick (WO 95/06470) in view of Sabbagh et al. and May record in the Final Office Action dated March 27, 2002 have been considered and found persuasive to remove this particular rejection since claims 36-59 are cancelled. Therefore, the said rejection is withdrawn.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 60-83 are rejected under 35 U.S.C. 102(b) as being anticipated by Scolnick (WO 95/06470).

Scolnick discloses methods of treating Alzheimer's disease or the onset of Alzheimer's disease in a human patient comprising administering to the said patient a therapeutically effective amount of a composition comprising an HMG-CoA reductase inhibitor, such as lovastatin, simvastatin, pravastatin, and fluvastatin. Scolnick also discloses that the HMG-CoA reductase inhibitor is administered by a controlled release dosage form. Note that the therapeutically effective amount of the HMG-CoA reductase inhibitor to be administered per day in the instant invention is also disclosed in Scolnick. Scolnick discloses that a drug that affects brain vasculature is useful in methods of treating Alzheimer's disease as well. See abstract, page 2 lines 16-20, page 10, and claims 1-25. Therefore, Scolnick's method inherently treats or reduces beta amyloid levels in a human which exhibits symptoms of Alzheimer's disease, as claimed herein since Scolnick's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389.

Thus, Scolnick clearly anticipates the claimed invention herein.

Applicant's remarks filed on July 29, 2002 in Paper No. 12 with respect to the rejection of claims 36-59 made under 35 U.S.C. 103(a) of record in the Final Office Action March 27, 2002 have been fully considered but are moot because claims 36-59 are cancelled by Applicants.

Additionally, Applicants argument that Scolnick fails to teach or suggest the claimed invention because there is no mention of beta amyloid ( $A\beta$ ) or any effect on  $A\beta$  by the administration of an HMG-CoA reductase inhibitor, is not found persuasive, since Scolnick clearly discloses that an HMG-CoA reductase inhibitor such as lovastatin, simvastatin, pravastatin, and fluvastatin is useful in a method of treating Alzheimer's disease in a human, although he merely proposes that the mechanism of action of the treatment therein is by reducing ApoE 4 levels. It is noted that the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps are already known even though applicant has proposed or claimed the mechanism. Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps.

Further, as discussed in the previous Office Actions July 3, 2001 and March 27, 2002, Alzheimer's disease is a well known APP processing disorder with increasing the amount of  $A\beta$  peptide in the brain, cerebral spinal fluid, or plasma of the mammal or  $A\beta$  peptide aggregation or plaque in the brain of the mammal according to Sabbagh et al. and May. Moreover, Applicants' own admission regarding the prior art in the "Background of the Invention" clearly teaches that it is known that Alzheimer's disease

is in the process of increasing the amount of A $\beta$  peptide in the brain, cerebral spinal fluid, or plasma of the mammal or A $\beta$  peptide aggregation or plaque in the brain of the mammal. Therefore, Scolnick's method which treats Alzheimer's disease inherently treats or reduces beta amyloid (A $\beta$ ) peptide levels in a human which exhibits symptoms of Alzheimer's disease.

The declaration of Dr. Edward Cullen under 37 CFR 1.132 submitted July 29, 2002 has been fully considered but are not deemed persuasive since the declaration primarily discusses that the mechanism of action of the treatment proposed by Scolnick – by reducing ApoE 4 levels is different from the one of the instant invention. As discussed above, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps are already known even though applicant has proposed or claimed the mechanism.

Additionally, the declaration herein is ineffective to overcome the previous 103(a) rejection herein since the declaration merely presents statements or conclusion regarding the different mechanism of action herein from the one in the cited prior art, but fails to set forth any factual evidences. Therefore, there is no clear and convincing evidence in support of Cullen's statements or conclusion in the declaration.

In view of the rejections to the pending claims set forth above, no claims are allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. A. Jiang, Ph.D.  
Patent Examiner, AU 1617  
November 15, 2002

  
SREENI PADMANABHAN  
PRIMARY EXAMINER  
11/18/02